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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,291

07/19/2006

Steven Paul Farrugia

3869/030 US

8885

22440 7590 01/04/2010
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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

01/04/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,291	Applicant(s) FARRUGIA, STEVEN PAUL	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/06, 11/6/08</u> . | 6) <input checked="" type="checkbox"/> Other: <u>translation of WO 00/74755</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Vega et al. (WO 00/74755, herein referred to as "Vega").

Regarding claims 1, 2, 16, and 17, Vega discloses a system and method for treating sleep disordered breathing (SDB) during successive treatment sessions , wherein the system provides CPAP during sleep (see abstract), the system comprising: a blower and a blower controller (turbine and controller; see abstract); a mask (see page 10, line 4 of the translation) for communicating pressurized air between the blower and a patient; and sensors for communicating signals indicative of pressure and flow to said controller (although Vega does not specifically disclose "sensors" the pressure levels are precisely adjusted by the controller and apnea events are determined by a percent reduction in flow rate and Vega discloses "measuring the pressure" in page 8, line 7; therefore, the device of Vega must inherently have a sensor that produces a signal indicative of pressure and flow rate); wherein the controller: controls a constant treatment pressure to be applied during a first session (see page 5, line 15 of translation); derives a sleep disorder index (SDI)/apnea hypopnea index (AHI) representative of the number of apnea and hypopnea events that occurred during said first session (see abstract and page 11, lines 1-5 of translation); determines if an increase in treatment pressure is required based upon said derived

Art Unit: 3771

SDI/AHI (see page 5, lines 16-22 of translation); and controls said increase in treatment pressure during a second, subsequent session if it was determined that an increase is required (see page 6, lines 1-2 of translation). Examiner notes that claim 16 appears to be drawn to an apparatus claim with process steps for the controller. Accordingly, the claim is being treated as an apparatus claim including functional limitations.

Regarding claims 3, 4, 10, 18, 19, and 26, Vega discloses that the controller determines apnea events when a short term moving average of ventilation drops below a long term moving average (reduction of 90% or more from NORMAL) for a minimum period of time (although Vega doesn't explicitly mention an amount of time, there is inherently a minimal amount of time for the comparison to occur to register the event) and hypopnea events when a short term moving average of ventilation drops between a first and second percentage of said long term average (30-40% of NORMAL) for a minimum period of time (see page 10, line 12-page 11, line 5 of translation).

Regarding claims 5, 11, 20, and 27, Vega discloses that if the index is less than a minimum number treatment pressure is lowered in said subsequent session (see page 13, lines 2-4 of translation).

Regarding claims 6, 12, 21, and 28, Vega discloses a rate of increase of treatment pressure in successive treatments that is greater than a rate of decrease of pressure in successive sessions (i.e., Vega discloses lowering the pressure by a "low value, for example 1 mbar" on page 9, line 14, while increasing the treatment pressure by larger rates such as 4 mbar on page 7, line 21-page 8, line 1).

Art Unit: 3771

Regarding claims 7, 13, 23, and 30, Vega discloses increasing said treatment pressure is the index was greater than a minimum number (see page 7, lines 21-22 of translation).

Regarding claims 8, 14, 24, and 31, Vega discloses increasing the treatment pressure by an amount that is a function of the magnitude of the derived index (see page 10, lines 1-4 of translation).

Regarding claims 9, 15, 25, and 32, Vega discloses increasing the treatment pressure if the index is greater than a minimum number as discussed above with respect to claims 7, 13, 23, and 30. The blower inherently has a maximum deliverable pressure; thus, if the pressure were above this value, the pressure could not be increased anymore.

Regarding claims 22 and 29, Vega discloses that if the index is less than a minimum number to maintain the pressure in a subsequent session (see page 6, lines 3-4 of translation).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Axe et al. (both references) and Rapoport et al. are cited to show other breathing systems with controllers that automatically adjust pressure in subsequent sessions by monitoring patient breathing and apnea episodes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

Art Unit: 3771

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Steven O. Douglas/
Primary Examiner, Art Unit 3771